PATENT COOPERATION TREATY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2004/005443	22.12.2004	23.12.2003

International Patent Classification (IPC) or both national classification and IPC
C08L5/08, A61L27/26

Applicant
INNOMED LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Form (PCT/ISA/237) (Cover Sheet) (January 2004)

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-5 658 915 (ABE ET AL) 19 August 1997
D2: US-A-5 496 933 (KELKENBERG ET AL) 5 March 1996
D3: US-B1-6 224 893 (LANGER ROBERT S ET AL) 1 May 2001

1. Novelty - Article 33(2) PCT

The subject-matter of **claims 1-14** is anticipated by D1.

D1 is directed to an antibacterial agent containing a polyelectrolyte complex (PEC) prepared by reacting a cationic polysaccharide (a4) like chitosan or a derivative thereof (see Preparation Examples 12-17) with an anionic polysaccharide (b3) like hyaluronic acid, which are crosslinked to each other by ionic bonds (between the N^+ sites of the cationic polymer and the acid sites of the anionic polymer, see column 4, lines 58-65) and form a gel which is insoluble in a solvent. The PEC may be shaped and processed in the form of a fibre, a film, a sheet, a block, a latex or a gel and used as an antibacterial material in a wet or dry state (see the passages cited in the International Search Report).

The formulation of **present claims 1 and 7** does not allow to distinguish the covalently crosslinked chitosan in which resides hyaluronic acid (see page 3, lines 10-21, of the description) from a ionic complex therefrom as disclosed in D1 since the type of the bonding is not specified. Moreover, one cannot exclude the presence of ionic bonds with hyaluronic acid even if the chitosan has been covalently crosslinked.

The Applicant chose to define the conditions to avoid protonation of the primary and secondary amine groups on the basic polysaccharide and the reaction of hydroxyl groups or any other functional group on the anionic polysaccharide in **process claim 7** by the result to be achieved (see the Guidelines 5.35). This is considered unclear (Article 6 PCT) and cannot thus be taken into consideration for the assessment of novelty.

2. Inventive step - Article 33(3) PCT

Since the subject-matter of claims 1-14 is not novel, the question of inventive step appears to be superfluous.

It should however be kept in mind that D3 points toward the use of polymer compositions of blends of covalently and ionically crosslinkable polymer like chitosan and hyaluronic acid which when exposed to radiation form semi-interpenetrating networks, the non-crosslinked polymer being able to diffuse. Biologically acitve material as for instance polysaccharides can also be added to said polymer compositions to be used for drug delivery.

This disclosure would lead the skilled person to the claimed subject-matter.

3. Industrial applicability - Article 33(4) PCT

3.1. The subject-matter of present **claims 1-10** appears to comply with the requirements of industrial applicability as stipulated in Article 33(4) PCT.

3.2. Claims 11-14 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

For the assessment of the present claims 11-14 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.